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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,926	09/16/2003	Michael E. Benz	P-10909.00	2299
26813	7590	09/26/2007		
MUETING, RAASCH & GEBHARDT, P.A. P.O. BOX 581415 MINNEAPOLIS, MN 55458			EXAMINER	
			SERGENT, RABON A	
			ART UNIT	PAPER NUMBER
			1711	
			MAIL DATE	DELIVERY MODE
			09/26/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/663,926

**Applicant(s)**

BENZ ET AL.

**Examiner**

Rabon Sergeant

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-70, 76 and 77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-70, 76 and 77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                                  |                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                             | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/16/07</u> . | 6) <input type="checkbox"/> Other: _____                                                |

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 16, 2007 has been entered.

2. It is noted that applicants' amendment of August 16, 2007 failed to comply with the requirements of 37 CFR 1.121 in that double brackets were used to denote deletion of greater than five characters in length.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

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ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-70, 76, and 77 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,984,700. Although the conflicting claims are not identical, they are not patentably distinct from each other because the R<sup>1</sup> groups within the claims of the patent encompass alkyl groups containing quaternary carbon groups.

5. Claims 1-70, 76, and 77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28, 30-34, 39, and 40 of copending Application No. 10/663,925. Although the conflicting claims are not identical, they are not patentably distinct from each other because the R<sup>1</sup> groups within the claims of the patent encompass alkyl groups containing quaternary carbon groups.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-70, 76, and 77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-46 and 48 of copending Application No. 11/133,627. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because the R<sup>1</sup> groups within the claims of the patent encompass alkyl groups containing quaternary carbon groups.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Applicants have stated that each of the obviousness-type double patenting rejections has been rendered moot in view of the amendments to the claims; however, applicants have not elaborated on this statement. Clarification and/or further explanation is required.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-70 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/07499 or WO 00/64971, each in view of Pinchuk ('240) or EP 821973.

Each of the primary references discloses polyurethane or polyurethane-urea polymers suitable for the production of medical devices, wherein the polymer is formed from a silicon-

containing polyol or polyamine wherein the silicon-containing group corresponds to that claimed and further wherein R groups containing quaternary carbons are specifically disclosed as being suitable linkages within the polyol or polyamine. Note the disclosure that the alkyl or alkylene groups may be 2,2-dimethylbutyl, 3,3-dimethylbutyl, 1,2,2-trimethylpropyl, 2,2-dimethylpentyl, 3,3-dimethylpentyl, 4,4-dimethylpentyl, and 1,1,3,3-tetramethylbutyl.

10. The primary references fail to teach a specific preference for the incorporation of these quaternary carbon-containing groups within the silicon group-containing polyol or polyamine; however, the advantages of incorporating such groups into polymer compositions to be used within medical applications was known at the time of invention. Pinchuk discloses that polymers having increased amounts of quaternary carbons are the most “medically” inert. See column 3, lines 60+ within Pinchuk (‘240) and page 3, lines 36-36 of EP 821,973. Therefore, in view of these secondary teachings disclosing the benefits of incorporating quaternary carbons into the polymer chain, the position is taken that one of ordinary skill, seeking a biostable polymer, would have been motivated to select and incorporate the disclosed quaternary-carbon containing groups of the primary reference as the R groups of the silicon-containing polyols or polyamines, so as to arrive at the instant invention. Furthermore, since the primary references establish the compatibility of the quaternary carbon-containing groups with the silicon-containing groups of the polyols or polyamines, the position is taken that it further would have been obvious to incorporate increased numbers of quaternary carbons or repeating quaternary carbon groups within the polyols or polyamines, so as to maximize the biostability of the final polymer.

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11. Applicants' response has been considered. As a result, the reliance on Meijs et al. and WO 98/54242 has been withdrawn. However, the rejection has been maintained for the following reasons. Firstly, the examiner does not agree that there is no enabling disclosure within the primary reference for the production of polymers having applicants' claimed structures. The primary references clearly disclose structures that correspond to applicants' claimed silicon-containing structures, and one of ordinary skill in the art would have expected them to function equivalently to siloxanes, based upon these disclosures. Secondly, in view of the preceding remarks, all of the disclosed silicon-containing structures are adequate to satisfy applicants' soft segment limitation. Thirdly, despite applicants' remarks concerning the secondary references, the position is maintained that the advantages disclosed within the secondary references with respect to the incorporation of quaternary carbons within biostable polymers would have motivated one of ordinary skill to select and utilize the quaternary carbon containing species of the primary references. The position is ultimately taken that applicants' have failed to fully appreciate the teachings of the secondary references concerning the desirability of incorporating quaternary carbons into biostable polymers. These teachings coupled with the fact that the primary references specifically disclose quaternary carbon group species as linkages within the silicon-containing polymers are sufficient to render the instant invention *prima facie* obvious. Applicants have argued that there is no disclosure within the silicon-lacking secondary references that would lead one to believe that polymers containing both silicon containing moieties and quaternary carbons are medically inert. In response, in view of the combined teachings of the primary and secondary references that deal with the biocompatibility of the respective polymers, one of ordinary skill would have reasonably

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expected that polymers that employ both of the argued structures would be beneficial from a medical point of view. Despite applicants' remarks, the position is taken that the evidence of obviousness outweighs the evidence of non-obviousness.

12. Claims 1-16 and 40-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/07499 or WO 00/64971, each in view of Pinchuk ('240) or EP 821973 and further in view of Kennedy ('973).

Each of the primary references discloses polyurethane or polyurethane-urea polymers suitable for the production of medical devices, wherein the polymer is formed from a silicon-containing polyol or polyamine wherein the silicon-containing group corresponds to that claimed. See abstracts.

13. The primary references fail to provide a specific teaching regarding the incorporation of quaternary carbon-containing groups within the polymer; however, the advantages of incorporating such groups into polymer compositions to be used within medical applications was known at the time of invention. Pinchuk discloses that polymers having increased amounts of quaternary carbons are the most "medically" inert. See column 3, lines 60+ within Pinchuk ('240) and page 3, lines 36-36 of EP 821,973. Furthermore, Kennedy teaches the use of polyols that are in rich quaternary carbons to produce polyurethanes. See column 1, lines 6-31; column 5, and column 10, lines 24+ within Kennedy. Therefore, in view of these secondary teachings disclosing the medical benefits of incorporating quaternary carbons into the polymer chain and the known use of such quaternary carbon group-containing reactants to produce polyurethanes, the position is taken that one of ordinary skill, seeking a biostable polymer, would have been motivated to incorporate the polyol of Kennedy into the polymers of the primary references, so




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as to obtain a medically improved polymer having an elevated amount of quaternary-carbon containing groups. In view of the definitions of the variables for the structure of applicants' claims, the position is taken that there is no requirement that the claimed quaternary carbons and silicon-containing groups stem from a single reactant.

14. Applicants' remarks have been considered; however, the position is maintained that the cumulative teachings of the respective references are adequate to motivate one to incorporate the respective silicon-containing groups and quaternary carbon-containing groups within the polyurethanes to be used in medical applications. Given the medical properties of the disclosed polyurethanes of the primary references and the teachings concerning quaternary carbon groups within the secondary references, including the disclosure within Kennedy that polyurethanes may specifically have quaternary carbons incorporated therein, the position is maintained that it would have been obvious to employ such groups within the polyurethanes of the primary references.

Any inquiry concerning this communication should be directed to R. Sergent at telephone number (571) 272-1079.

  
RABON SERGENT  
PRIMARY EXAMINER

R. Sergent  
September 20, 2007